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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,598	09/10/2003	Miri Seiberg	JBP-430-CIP1	5368
27777	7590	05/12/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1614	
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			05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,598	Applicant(s) SEIBERG ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/17/08;3/24/08;2/25/08;7/16/07;5/17/07;11/30/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed **5/17/07** presents remarks and arguments to the office action mailed **2/26/07**. Examiner notes the inconsistency between the claims as filed on August 21, 2006 and the remarks to the extent that claims 1-10 and 63 have not been identified as cancelled on the claim sheet. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/7/08; 3/24/08; 2/25/08; 7/16/07; 11/29/07 and 5/17/07 are acknowledged and have been reviewed. However, IDs dated 7/16/07, 11/29/07 and 2/25/08 have items that are not considered by the Examiner because they do not have a publication date or year or it is a duplicate of already acknowledged IDS.

Status of claims

Claims 73-86 are pending.

Allowable Subject Matter has been withdrawn based on the new rejection

Claims 73-76 allowed are now withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 79-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “from about”, “at least about” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether “from” (a lower limit) or “about”(broadening limitation, both higher and lower) controls the metes and bounds of the phrase “from about”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meybeck et al., US 5,034,228 in view of Sessa et al. JAOCS vol. 69 (3) 1992, 209-212 and Seiberg et al. J. Invest. Dermatol. 109:370-376 1997.

Meybeck et al., teach treating acne with soya lecithin and tretinoin. It is a known knowledge to one of ordinary skill in the art that soya lecithin is extracted from soybean or soybean powder, absent factual evidence, therefore claims 73- 74 and 76-78 are obvious variations of soybean extract. See col. 3, lines 36-38 and lines 61-64. With regard to claim 75, the reference teaches retinol as vitamin A, see col. 2, line 42. As to the soybean extract having trypsin inhibitory activity it is known in the art that soy products have varying trypsin inhibitory activity as discussed below by Sessa et al.

Sessa et al teach soy products with varying trypsin activity inhibitor. See reference enclosed. (the reference used merely to show that soy products do contain trypsin –inhibiting activity). Please note that nondenatured soybean extract encompasses soybean lecithin which is known in the art to have trypsin activity inhibitor.

Seiberg et al. teach cell death of acne is eliminated by trypsin treatment and that trypsin might increase the therapeutic value of acne treatment and improve skin elasticity while reducing irritating effect. Thus one of ordinary skill in the art would be motivated to add a trypsin –inhibiting activity agent to the composition as taught in the prior art. See entire abstract.

It would have been obvious to one of ordinary skill in the art to have treated acne with a retinoid compound such as tretinoin and retinol in combination with a soy product having trypsin inhibitor because as taught by Seiberg et al. trypsin increase the therapeutic value of acne treatment and improve skin elasticity while reducing irritating effect. One of ordinary skill in the art would have been motivated to use a trypsin inhibitor such as a soy extract with either tretinoin or retinol because it is known in the art.

Claims 79-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meybeck et al., US 5,034,228 in view of Sessa et al. JAOCS vol. 69 (3) 1992, 209-212 and Seiberg et al. J. Invest. Dermatol. 109:370-376 1997 as applied to claims 73-78.

The references and teachings are applied here as above.

Meybeck teaches 2 g of soy lecithin and 0.1 g of tretinoin which examiner has interpreted to be within the claim invention of 79, 81-83 and 85-86. See col. 3, line 62. One of ordinary skill in the art would be motivated to optimize the concentration of the active agents for the treatment of acne because it is known in the art that topical application of the retinoids in the past gave undesirable effects such as irritation. See col. 1, lines 48-56 (meybeck et al). Based on that the determination of a dosage having the optimum therapeutic index is well within the level of the ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get the maximum effect of the drug, hence the reference makes obvious the instant invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG

4/22/08

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614